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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,561	09/15/2003	Nancy D. Denslow	5853-238	3958

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EXAMINER	
SALMON, KATHERINE D	
ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/663,561	DENSLOW ET AL.	
	Examiner	Art Unit	
	Katherine Salmon	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *33-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☒ Claim(s) *1-32* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to papers filed 7/16/2007. Currently Claims 1-39 are pending. Claims 33-39 are withdrawn as being drawn to a nonelected invention.

2. This action for Claims 1-32 contains reiterated rejections and newly made rejections. Specifically USC 112/1st paragraph Enablement has been added. Response to arguments follows.

3. This action is NONFINAL.

Withdrawn Rejections

4. The rejection of the claims made under 35 USC 112/Written Description made in section 9 of the previous office action is moot in view of the amendments to the claims.

5. The rejection of the claims made under 35 USC 102(b) made in section 10 of the previous office action is moot in view of the amendments to the claims.

Maintained Rejections and Rejections Necessitated by Amendment

Priority

6. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. [1] as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/410,414, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Claims 1-32 are drawn to a method for detecting comprised of analyzing specifically identified SEQ IDs. These genes or gene fragments are not listed in Application No. 60/410,414. Accordingly Claims 1-32 are not entitled to the benefit of the prior application.

Response to Argument

The reply filed 1/05/2007 and 7/16/2007 do not provide any argument to the denial of benefit of Claims 1-32 to Application No. 60/410,414. The filing date of the instant application therefore is 09/15/2003.

Claim Objections

7. Claims 1-32 are objected to because they specifically recite nonelected subject matter. The Claims require "at least one gene encoded by a nucleotide sequences, selected from the group consisting of SEQ ID NO's: 146, 148, 149, 166, 167, 178, 194,

199, 200, 207, 285, 347, 424, 489, 505, 509, 516, 519, 532-534, 542, 545, 551, 529 for identifying estrogen activity and SEQ ID NO's 14, 15, 25, 28, 30, 42, 44, 47, 52, 61, 62, 71, 558, and 555". As stated in the response to the restriction filed 12/25/2005, applicant has elected a specific combination of SEQ ID NO's: 146, 148, 149, 166, 167, 178, 194, 199, 200, 207, 285, 347, 424, 489, 505, 509, 516, 519, 532-534, 542, 545, 551, 529 for identifying estrogen activity and SEQ ID NO's 14, 15, 25, 28, 30, 42, 44, 47, 52, 61, 62, 71, 558, and 555. Applicant should amend the claims so that the claims are directed to the elected invention of the specific combination of genes.

Prior to allowance of these claims, the non-elected subject matter will be required to be deleted from the claims.

Response to Arguments

The reply traverse the objection. The reply asserts that both sets of SEQ IDs are essential for the invention (p. 12 2nd paragraph). This argument has been fully considered but has not been found persuasive. The response to the restriction filed 12/25/2005, applicant has elected a specific combination of SEQ ID NO's: 146, 148, 149, 166, 167, 178, 194, 199, 200, 207, 285, 347, 424, 489, 505, 509, 516, 519, 532-534, 542, 545, 551, 529 for identifying estrogen activity and SEQ ID NO's 14, 15, 25, 28, 30, 42, 44, 47, 52, 61, 62, 71, 558, and 555. Therefore, applicant elected a specific combination of SEQ ID NO's: 146, 148, 149, 166, 167, 178, 194, 199, 200, 207, 285, 347, 424, 489, 505, 509, 516, 519, 532-534, 542, 545, 551, 529 and SEQ ID NO. 14, 15, 25, 28, 30, 42, 44, 47, 52, 61, 62, 71, 558, and 555. However, as the claims are

drawn to analyzing at least one gene selected from the group consisting of 146, 148, 149, 166, 167, 178, 194, 199, 200, 207, 285, 347, 424, 489, 505, 509, 516, 519, 532-534, 542, 545, 551, 529 and SEQ ID NO's 14, 15, 25, 28, 30, 42, 44, 47, 52, 61, 62, 71, 558, and 555. Therefore, the claims as written are drawn to multiple combinations of SEQ ID Nos, however, the response to the restriction filed elected one specific combination. It is suggested to remove this objection that the claims be amended such the claims are drawn to the elected combination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-32 are unclear. The claims are drawn to gene encoded by a nucleotide sequence selected from the group of SEQ ID Nos. It is unclear if each gene is represented by one SEQ ID or if each gene is represented by more than one SEQ ID. In the reply for restriction (12/22/2006) applicant elected the specific set of SEQ IDs listed in the instant claims. Therefore it is unclear if the expression of at least one gene would reflect the expression of all the elected SEQ ID Nos.

Response to Arguments

The reply traverses the rejection. The reply asserts that each SEQ ID No. represents one different gene (p. 13 2nd paragraph). This argument has been fully considered but has not been found persuasive. The response to restriction (12/22/2006) applicant elected a specific combination of 39 SEQ ID Nos. Claim 1, however, is drawn to expression of at least one gene encoded by a nucleotide sequence from the group consisting of the SEQ ID Nos. Therefore, the claim is not drawn to the specific combination of SEQ ID Nos. This is further evident based on the depended claims that are drawn to "at least 3 genes", "at least 4 genes", ect. These combinations of genes would not encompass all of the elected 39 SEQ ID Nos. It is suggested the claims be amended to reflect the elected combination of SEQ ID Nos.

Claim Rejections - 35 USC § 112-Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 and 10-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention and breadth of claims

Claims 1-7 are drawn to a method for detecting the presences of an agent having estrogenic or androgenic activity in a sample, comprising providing at least one sheepshead minor or large mouth bass fish cell exposed to the sample and analyzing for expression of a combination of SEQ IDs by comparing the expression of the cell to a control cell. Claims 8-9 define the cell. Claim 10 defines the fish cell. Claim 11 is drawn to a method comprising isolating RNA transcripts. Claim 12 is drawn to expression comprises contacting the isolated RNA transcripts. Claim 13 and 14 are drawn to a method wherein the probe is immobilized on a substrate. Claims 15-20 are drawn to a method wherein the step of analyzing the at least one fish cell for expression of a combination of genes further comprises contacting the isolated RNA transcripts or nucleic acids derived with different probes that each hybridize to a different nucleotide sequence selected from a combination of genes. Claim 21 and 22 are drawn to a method wherein the at least one probe or the isolated RNA transcripts or nucleic acids are conjugated with a detectable label. Claim 23 is drawn to a method comprising analyzing the control cell not exposed to the sample having estrogenic or androgenic activity for expression of a combination of genes. Claim 24-27 are drawn to a method

comprising analyzing the control cell not exposed to the sample having estrogenic or androgenic activity for expression of probes of a combination of genes and isolating RNA transcripts wherein the fish cell has a detectable label and the RNA transcripts have a second detectable label. Claim 28 is drawn to a method of comparing the expression of the at least one nucleic acid in the cell with the expression of the control cell. Claim 29 is drawn to a method comprising contacting the at least one fish cell with a sample prior to analyzing the expression level. Claim 30 is drawn to a method wherein the sample comprises water. Clam 31 is drawn to a method comprising providing a fish and contacting the fish with the sample. Claim 32 is drawn to a method for determining if an agent has estrogenic, anti-estrogenic, androgenic, or anti-androgenic activity comprising contacting at least one fish cell with an agent and analyzing the expression level of a combination of genes.

The claims are drawn to a method of detecting the presence of ANY agent having estrogenic or androgenic activity by analyzing the expression of a selected combination of SEQ ID Nos and comparing the expression to a control cell wherein ANY difference in the level of expression is indicative of an agent.

However, as discussed below, the specification discloses that there is a specific level of expression under expressed or over expressed for various agents. As discussed below the specification discloses that different agents have different expression values for the elected combination of SEQ ID Nos. Further, the art teaches that correlating expression levels to traits have a high degree of unpredictability.

The invention is in a class of invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Fed. Cir. 2001).

Guidance in the Specification

The specification discloses that based on up-regulated or down-regulated genes a determination of estrogenic or androgenic agent can be determined (p. 2 lines 10-15). The specification discloses a screening assay to characterize the hormonal activity of fish cells is developed which the effect of the agent on gene expression is compared to known patterns of gene up-regulation or down-regulation (p. 2 lines 22-25).

The specification discloses a series of gene expression profiles from Sheepshead minnow cells that have been exposed to E2, EE2, diethylstilbestrol (DES), paranonylphenol (pNP), methoxycholor (MXC), or endosulfan (ES) and control fish (p. 6 liens 22-30 and Figures 1-2).

The specification discloses that any clone above 1.66 was considered up-regulated and any clone below 0.42 was considered down regulated (p. 6 liens 29-31 and p. 7 lines 1-5).

The specification discloses gene expression profiles from control and E2 treated large mouth bass fish (p. 7 lines 24-25). The specification asserts that any genes changed by more than two-fold were considered to be up or down regulated (p. 7 lines 29-30).

Therefore, the specification seems to be asserting that depending on which cell type (e.g. Sheepshead minor or Largemouth bass) a different expression level is considered up regulated or down regulated. For example in the presence of E2 a sheepshead minnow cell expressing a gene at above 1.66 would be considered up regulated, however, a large mouth bass fish cell would not be considered up regulated because these cells must change by more than a two-fold difference. Therefore it is unpredictable that any level of expression would be correlative to detection of an estrogenic or androgenic agent. The specification discloses that only particular fold

differences, which are specific for each type of cell, are correlative to up or down regulation of the gene.

The specification asserts the detection of the presence of several estrogenic or androgenic agents such as E2, EE2, DES, MXC, ES, 4-NP, p-chlorophyeyl and p,p'-DDE (p. 17 lines 15-20). However the estrogenic or androgenic may including any other hormonally active agent including benzenehexachloride, 1,2-dibromethane, chloroform, dioxins, furans, octachlorostyrene, PBBs, PCBs, and PCB (p. 17 lines 15-22).

Therefore the specification discloses a large number of potential agents, which would have some effect on the elected group of SEQ ID Numbers. It is unpredictable, however, that the same correlative effect on the group of SEQ ID Numbers is observable on all estrogenic or androgenic agents. As discussed in the working examples, below, the specification indicates that there are different expression level changes based on the type of agent in which the fish cell is exposed. Therefore it is unpredictable that the same expression level changes are predictive for any estrogenic or androgenic agents.

Working Examples

The examples provided by the specification teach arrays for expression profiling. The first example teaches the expression profiling of estrogenic compounds using mRNA from a sheepshead minnow (p. 26 lines 21-22). The cells were exposed to EE2, DES, E2, pNP, or MXC (p. 27 lines 1-5). The expression of the genes were determined by comparison to a control. Genes with 1.66 fold induction were designated as up regulated and values below 0.42 as down-regulated (p. 28 lines 28-31).

The specification asserts that of the 30 genes on the array, 6 genes were up-regulated by E2 and 3 genes were down regulated by E2. However the claims are drawn to 25 SEQ ID Numbers for identifying estrogen activity. The specification does not indicate which of these SEQ ID Numbers are up regulated or down regulated. The skilled artisan would have to perform undue experimentation to determine which SEQ ID Nos are correlative to the presence of an agent having estrogenic activity.

The specification assert that not all of the 9 genes up or down regulated in the presence of E2 were similar with all estrogenic agents (p. 29 lines 6-15). Therefore it is unpredictable that the detection of the under or over expression of the elected SEQ ID Numbers would be correlative to detection of any estrogenic agent, because each estrogenic agent seems to have a different expression profile. The skilled artisan would have to perform undue experimentation to determine which up or down regulated expression was correlative to the detection of each estrogenic agent.

The specification also teaches a largemouth bass array to monitor exposure of fish to 4-NP (p. 34 lines 9-11). The specification teaches a set of genes were up regulated by 2-fold or greater or down regulated by 2 fold or greater (p. 34 lines 30-31 and p. 35 lines 1-2).

The specification discloses juvenile large mouth bass were treated with 11-KT (11-ketotestosterone) or DHT (dihydrotestosterone) (p. 38 liens 1-10). The specification asserts that the genes were detected for up or down regulation (Tables 1 and 2).

Table II and III represent genes up or down regulated in response to estrogenic agents (p. 40). However, the table does not teach which genes were up regulated or down regulated nor which estrogenic agents were present. Based on the disclosure of the specification it would be unpredictable that each estrogenic agent tested had the sample expression pattern because the specification indicates that not all genes were

up or down regulated in the presence of all estrogenic agents. Further, the specification provides no support which of the SEQ ID Numbers that have been elected are up regulated or down regulated.

Further Figure 1, seems to indicate that there are different expression level profiles dependent on the estrogen agent. Therefore it is unpredictable that all estrogenic agents have the same correlative expression levels.

Table I also indication if the gene was up or down regulated using 11-KT and DHT (androgenic agents). The table shows that some of the SEQ ID Nos elected are up regulated or down regulated by both androgenic agents. For example SEQ ID NO. 25 is up regulated by both of the androgenic agents (p. 41 LMB_SOL-CART-25A#5). Some SEQ ID Nos only shows up regulation or down regulation with one agent not with both androgenic agents. For example SEQ ID NO. 28 is up regulated in the presence of DHT (p. 41 LMB-CIS-RETIN DEHYDRO). Therefore, the specification discloses the expression profile of the elected SEQ ID Numbers is different depending on the androgenic agent exposure. Therefore it is unpredictable that any androgenic agent can be detected by detecting any expression level changes of the elected combination of SEQ ID Numbers because each agent seems to be correlative to a different expression profile.

Quantity of Experimentation

The quantity of experimentation in this area is extremely large since there is significant number of parameters which would have to be studied the skilled artisan would have to test each species of fish individually to determine if a cell from a specific species (e.g. Large mouth bass or sheepshead minnow) would provide adequate

expression data to detect any androgenic or estrogenic compounds. The skilled artisan would need to determine which SEQ ID Numbers were correlative to over or under expression in the presence of any estrogenic agent or androgenic agent.

This would require a large amount of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

The unpredictability of the art and the state of the prior art

The state of the art teaches that there is a natural variation in gene expression among different individuals and the difficulty in applying gene expression results. The art of Cheung et al (Nature Genetics 2003 Vol. 33 p. 422) teaches that there is natural variation in gene expression among different individuals. Cheung et al teaches an assessment of natural variation of gene expression in lymphoblastoid cells in humans, and analyzes the variation of expression data among individuals and within individuals (replicates) p.422, last paragraph; Fig 1). The data indicates that, for example, expression of *ACTG2* in 35 individuals varied by a factor of 17; and that in expression of the 40 genes with the highest variance ratios, the highest and lowest values differed by a factor of 2.4 or greater (Fig 3).

The unpredictability of correlating gene expression level to any phenotypic quality is taught in the prior art of Wu (Journal of pathology 2001 Vol. 195 p. 53). Wu teaches that gene expression data, such as microarray data, must be interpreted in the context of other biological knowledge, involving various types of 'post genomics' informatics, including gene networks, gene pathways, and gene ontologies (p.53, left col.). The

reference indicates that many factors may be influential to the outcome of data analysis, and teaches that expression data can be interpreted in many ways. The conclusions that can be drawn from a given set of data depend heavily on the particular choice of data analysis. Much of the data analysis depends on such low-level considerations as normalization and such basic assumptions as normality (p.63 - Discussion). The prior art of Newton et al (Journal of Computational Biology 2001 Vol. 8 p. 37) further teaches the difficulty in applying gene expression results. Newton et al teaches that a basic statistical problem is determining when the measured differential expression is likely to reflect a real biological shift in gene expression, and replication of data is critical to validation (p.38, third full paragraph). Therefore it is unpredictable with regard to a method of diagnosing depression which gene expression data would be considered a positive correlation with depression. Further, the specification provides no results indicating the fold difference between subjects, which would be considered an association of a gene with depression. The skilled artisan would have to perform undue experimentation to determine which expression levels in each gene would be positively correlated to depression and which changes in expression levels are due to individual differences in the subjects.

Level of Skill in the Art

The level of skill in the art is deemed to be high.

Conclusion

In the instant case, as discussed above, in a highly unpredictable art the specification indicates that expression levels vary base on species type and androgenic or estrogenic agent type it is unpredictable to correlate any expression level change with the detection of any agent with estrogenic or androgenic activity. The claims broadly encompass any estrogenic or androgenic agent, whereas the specification indicates that these agents have differing effects of expression of the elected combination of SEQ ID Numbers. The claims broadly encompass any level of expression however, the specification asserts that only genes 1.66 or higher are over expressed in sheepshead minnow and only genes that differ by at least 2 fold are over expressed in large mouth bass. Given the broad claims in an art whose nature is identifies as unpredictable, the unpredictability of that art, the large quantity of research required to define these unpredictable variables, the lack of guidance provided in the specification balanced only against the high skill level in the art, it is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

Response to Arguments

The reply traverses the rejection. The reply indications that based on the scope of enablement the claims have been amended to the detection of only sheepshead minnow and large mouth bass fish and the analysis of nucleotide sequences form the specific combination of elected SEQ ID Numbers. However, based on further consideration a newly applied lack of enablement has been applied. Therefore this action has been made nonfinal.

Conclusion

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine Salmon whose telephone number is (571) 272-3316. The examiner can normally be reached on Monday-Friday 8AM-430PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Salmon
Examiner
Art Unit 1634

/Jehanne Sitton/
Primary Examiner
9/26/2007